

## A P P E N D I X

### Marked-Up Version of Changes

#### IN THE CLAIMS:

The claims are being amended as follows:

Claim 1. (Amended) A method of preparing products [containing] comprising moisture-sensitive biologically active ingredients [materials, including biological materials such as proteins, peptides or live cells,] comprising at least the steps:

- (i) providing a coating liquid comprising at least one moisture-sensitive biologically active ingredient [active], a sugar polymer and a water soluble/miscible solvent;
- (ii) providing [a quantity of] microparticles comprising at least water soluble gel forming solid particles;
- (iii) fluidizing said [quantity of] microparticles within a processing chamber of a suitable apparatus to form a fluidized bed of said microparticles;
- (iv) spraying said coating liquid onto said fluidized bed from beneath the fluidized bed to coat said microparticles [therewith] with said coating liquid under saturated moisture conditions; and
- (v) allowing the resulting coated microparticles to dry.

Claim 2. (Amended) [A] The method according to claim 1, [wherein] additionally comprising one or more additional coating steps to further coat the microparticles with at least one of an

enteric coating, a film coating, a moisture repellant coating, [and/or] and a taste-masking coating.

Claim 3. (Amended) [A] The method according to claim 1, [or 2] wherein in step (v) the resulting microparticles are heat dried.

Claim 4. (Amended) [A] The method according to [any one of claims] claim 1, [to 3] wherein the active ingredient comprises one or more proteins, peptides[,] or cells.

Claim 5. (Amended) [A] The method according to [any one of claims] claim 1, [to 4] wherein the water soluble/miscible solvent is glycerol, propylene glycol, or a combination of glycerol and propylene.

Claim 6. (Amended) [A] The method according to [any one of claims] claim 1, [to 5] wherein the sugar polymer is selected from [a] the group [comprising] consisting of dextran, fructose, fruitose, glucose, invert sugar, lactitol, lactose, maltitol, maltodextrin, maltose, mannitol, sorbitol, sucrose, trehalose, isomalt, xylitol[,] and polydextrose, or a combination thereof.

Claim 7. (Amended) [A] The method according to [any one of claims] claim 1, [to 6] wherein the water soluble gel forming solid particles [comprising one or more water soluble gel forming solid particles] comprise a member selected from [a] the group [comprising] consisting of acrylate [and] or derivatives thereof, albumin, alginates, carbomers, carrageenan, cellulose [and] or derivatives thereof, dextran, dextrin, gelatine, polyvinylpyrrolidone[,] and starch.

Claim 8. (Amended) [A] The method according to [any one of claims] claim 1, [to 7] wherein the method is conducted in a moisture saturated environment.

Claim 9. (Amended) [A] The method according to [any one of claims] claim 1, [to 8] wherein the method is conducted in an oxygen free environment.

Claim 10. (Amended) [A] The method according to [any one of claims] claim 1, [to 9] wherein the resulting coated microparticles are formed into a composition for injection, as a sublingual tablet, as an oral tablet, as a sustained release sublingual tablet, into microcapsules, pessaries, preconstituted solid dose for nasal spray, nasal [or] drops, aqueous drops, eye wash, [or] eye drops, skin washing solutions[, ] or as a feed premix.

Claim 11. (Amended) [A] The method according to [any one of claims] claim 1, [to 9] wherein [the] said [is a] method is useful for stabilizing [biological materials] biologically active ingredients.

Claim 12. (Amended) [A] The method according to [any one of claims] claim 1, [to 11] wherein the microparticles [are] have a particle size of 50 microns to one millimeter [millimetre particle size].

Claim 13. (Amended) [A] The method according to [any one of claims] claim 1, [to 12] wherein the active ingredient is a hormone, cytokine or growth factor or a combination of any two or more thereof.

Claim 14. (Amended) [A] The method according to claim 13, wherein the active ingredient is selected from the group consisting of a human growth hormone, [or] an animal growth [hormones] hormone, a human growth hormone derivative, an animal growth hormone derivative [or derivatives thereof], erythropoietin, calcitonin, interferon, interleukin, insulin[, or] and a colony stimulating factor.

Claim 15. (Amended) [A] The method according to [any one of claims] claim 1, [to 12] wherein the active ingredient is an enzyme.

Claim 16. (Amended) [A] The method according to claim 15, wherein the enzyme [comprises] is selected from the group consisting of streptokinase, muramidase, [pancreas] pancrease, amylase, protease, lypase, cellulase, bromelain[, or] and papain.

Claim 17. (Amended) [A] The method according to [any one of claims] claim 1, [to 12] wherein the active ingredient is glucan.

Claim 18. (Amended) [A] The method according to claim 17, wherein said glucan is  $\beta$ -1,3-glucan.

Claim 19. (Amended) [A] The method according to [any one of claims] claim 1, [to 12] wherein the active ingredient is a microorganism.

Claim 20. (Amended) [A] The method according to claim 19, wherein the microorganism is one or more of *Bifidus*[,] or *Lactobacilli*.

Claim 21. (Amended) A product [when] produced by [a] the method according to any one of claims 1 to 20.

Claim 22. (Amended) A composition comprising a core of microparticles coated with [an] a moisture-sensitive biologically active ingredient and sugar polymer coating layer.

Claim 23. (Amended) [A] The composition according to claim 22, [which is] wherein said microparticles are further coated with at least one of an enteric coating, a film coating, a moisture repellent coating[,], and a taste-masking coating[, or one or more such coatings].

Claim 24. (Amended) [A] The composition according to claim 22, [or 23] wherein the active ingredient comprises [a protein, peptide, or cell] one or more proteins, peptides or cells.

Claim 25. (Amended) [A] The composition according to claim 24, wherein the active ingredient is a hormone, cytokine, or growth hormone, or a combination of any two or more thereof.

Claim 26. (Amended) [A] The composition according to claim 25, wherein the active ingredient is selected from [a] the group [comprising] consisting of a human growth hormone, [or] an animal growth [hormones] hormone, a human growth hormone derivative, an animal growth hormone derivative [or derivatives thereof], erythropoietin, calcitonin, [and] interferon, [and] interleukin, insulin[,] and a colony stimulating factor.

Claim 27. (Amended) [A] The composition as claimed in claim 24, wherein the active ingredient is a microorganism.

Claim 28. [A] The composition as claimed in claim 27, wherein the microorganism is one or more of *Bifidus*[,] or *Lactobacilli*.

Claim 29. (Amended) [A] The composition as claimed in [any one of claims] claim 22, [to 24] wherein the active ingredient is an [antidiarrhoea] antidiarrhea agent.

Claim 30. (Amended) [A] The composition as claimed in [any one of claims] claim 22, [to 24] wherein the active ingredient is a growth promotant.

Claim 31. (Amended) [A] The composition as claimed in [any one of claims] claim 22, [to 30 which] wherein said composition comprises microparticles comprising a member selected from the group consisting of acrylate[,] or derivatives thereof, albumin, alginates, carbomers, carrageenan, cellulose[,] or derivatives

thereof, dextran, dextrin, gelatin, polyvinylpyrrolidone[, or] and starch.

Claim 32. (Amended) [A] The composition as claimed in [any one of claims] claim 22, [to 31] wherein said composition is in the form of an injection, as a sublingual tablet, as an oral tablet, as a sustained release sublingual tablet, microcapsules, pessaries, preconstituted solid dose for nasal spray, nasal [or] drops, aqueous drops, eye wash, [or] eye drops, skin washing solutions, or as a feed premix.

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